



Health Protection Agency, Porton Down  
and  
European Collection of Cell Cultures

This document certifies that  
Virus RAdEs  
Deposit Reference 04121701

has been accepted as a patent deposit, in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on  
17 December 2004

.....  
Dr D H Lewis  
General Manager  
ECACC

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

DR. S. BHATTI

NATIONAL INSTITUTE OF IMMUNOLOGY  
VIBHAWI LABORATORYNEW DELHI  
110 067  
INDIANAME AND ADDRESS  
OF DEPOSITOR

## I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
DEPOSITOR:  
KACBESAccession number given by the  
INTERNATIONAL DEPOSITORY AUTHORITY:  
04121701

## II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

A scientific description  
 A proposed taxonomic designation

(Mark with a cross where applicable)

## III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above,  
which was received by it on 17 December 2004 (date of the original deposit):

## IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International  
Depository Authority on (date of the original deposit) and  
a request to convert the original deposit to a deposit under the Budapest Treaty  
was received by it on (date of receipt of request for conversion)

## IV. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr D H Lewis

Address: FCAAC  
HPR  
Filton Down  
Salisbury SP4 0QGSignature(s) of person(s) having the power  
to represent the International Depository  
Authority or of authorized officials(s):

Date: 27/1/05

Where Rule 6.4(d) applies, such date is the date on which the status of international depositary  
authority was acquired

Form BPI/4 (sole page)

1991

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## INTERNATIONAL FORM

120 2000 1998  
120 2000 1998  
NATIONAL INSTITUTE OF IMMUNOLOGY  
VIROLOGY LABORATORY

VIABILITY STATEMENT  
Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
Identified on the following page

120 2000 1998  
120 2000 1998  
NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

1. DEPOSITORY	II. IDENTIFICATION OF THE MICROORGANISM
120 2000 1998 Name: DR B VRATTI NATIONAL INSTITUTE OF IMMUNOLOGY VIROLOGY LABORATORY	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: 04121701
Address: 120 2000 1998 NEW DELHI 110 067 INDIA	Date of the deposit or of the transfer: 17 December 2004

## VIABILITY STATEMENT

120 2000 1998  
The viability of the microorganism identified under II above was tested  
120 2000 1998 17 December 2004. On that date, the said microorganism was

120 2000 1998 visible

120 2000 1998 no longer viable

120 2000 1998  
Indicate the date of the original deposit or, where a new deposit or a transfer has been  
made, the most relevant date (date of the new deposit or date of the transfer).  
120 2000 1998  
in the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability  
test.

120 2000 1998  
Mark with a cross the applicable box.

120 2000 1998 Form B7/4 (first page)

## IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED \*

The Virus Deposit Report and its Accession Number 04121701 was tested according to the Depositor's protocol and shown to be infectious and viable.

## V. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr D H Lewis ECACC HFA	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):
Address: Porton Down Salisbury Wiltshire SP4 0JG	Date: 27/1/05

Fill in if the information has been requested and if the results of the test were negative.  
Form BP/9 (second and last page)

# Patent Deposit Accession Form

## Virus

### DEPOSITOR INFORMATION

Name of Depositor/Company/Institute .. **NATIONAL INSTITUTE OF IMMUNOLOGY** ..

(NB this will be the name that appears on certification)

Contact Name .. **DR. SUDHANSHU VRATI** ..

Depositor Address **NATIONAL INSTITUTE OF IMMUNOLOGY, NEW DELHI-110067** ..

Tel No +91-11-26703696 .. Fax No +91-2-26162125 Email **vrati@niil.res.in**

### BIOHAZARD STATEMENT MUST BE ENCLOSED

*The deposit is made in accordance with the terms of the Budapest Treaty 1977. I agree to abide by the conditions and regulations regarding the deposit of cell lines to the ECACC.*

Signature .. *S. M. L.* .. Date .. **16-JUNE-2004** ..

Address to which invoice should be sent (if different from above)

**DIRECTOR,**  
**NATIONAL INSTITUTE OF IMMUNOLOGY,**  
**NEW DELHI-110067**

### VIRUS INFORMATION

Name in full **Recombinant Human adenovirus** ..

Abbreviated Name .. **RAdEs** .. Identification on Ampoules .. **RAdEs** ..

Strain .. Serological Type ..

Normal Host ..

Virus Titre Deposited ..

### VIRUS PROPAGATION

Host cells (first choice) .. **Human embryonic kidney 293 cells** ..

Alternative Host Cells .. **None** ..

Details of Host Cell Growth (media, temperature, seeding density, growth factors etc) *Grown in 100 mm monolayers of*  
**HEK 293 cells cultured in DMEM+10% FCS.**

Details of Virus Growth (eg confluence of host cells, co-cultivation, moi, effects, time taken) *At moi 0.1 it takes 2-36 hr*

*For CPE to appear cells are then harvested & virus prepared.*

### VIRUS STORAGE

Material stored (eg supernatant, infected cell extract, viable infected cells etc)

Temperature and conditions .. **Infected cell extract**, to be stored at -70°C

### VIRUS ASSAY

Method (enclose if necessary) *Plaque assay on 293 cells.*

### LITERATURE REFERENCES (if any)

### ANY OTHER RELEVANT INFORMATION

Please Note: ECACC must receive full information regarding delivery at least 48 hours before despatch.

A Biohazard Risk Assessment must be completed in order for your samples to be accepted. ECACC is required to assess the GMO status of all deposits PRIOR to receipt. Therefore, we will contact all depositors to advise them when we can receive samples.

2. Does the GM agent contain/produce a biologically active substance that could potentially cause harm to humans (eg toxin, cytokine, hormone, allergen, oncogene)

Yes

No

3. What is the likelihood that the genetic modification can confer pathogenic traits in the host organism?

Negligible	Possible	Probably or Demonstrated
✓		

If "possible", "probably" or "demonstrated" please provide additional details:

.....

4. What is the potential for sequences within the GM being transferred to another related microorganism?

Negligible	Low	Medium	High
✓			

If "medium" or "high" please provide additional details:

.....

5. In the light of your knowledge of this GMM and its origination, what is your assessment of its potential to cause harm to human health in the event of exposure?

Negligible	Low	Medium	High

If "medium" or "high" please provide additional details:

.....

6. Does this GMM have the ability to survive, establish and disseminate in the environment?

Yes

No

Form completed by: Name:

..... DR. SUDHANSU VRAT!

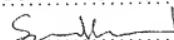
Title:

..... STAFF SCIENTIST

Date:

..... 16TH JUNE 2004

Signature:

..... 

..... All details above are correct

ECACC may request further information in order to complete its risk assessment. To whom should such requests be addressed?

Name: ..... DR. G. W. BOTH

Telephone: ..... +61-2-9490 5169

Fax: ..... +61-2-9490 5005

E-mail: ..... Gerry.Both@csiro.au

ECACC/2001/013





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